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JAN 25 2007REMARKS/ARGUMENTS

Claims 1-4 remain in this application. Claim 1 has been amended. Claims 5-8 were withdrawn as the result of an earlier restriction requirement and have been canceled.

Claim 1 has been amended to further clarify the language "enhancer peptide" and "peptide fragment". Enhancer peptide is discussed on page 5, lines 1-8. "Peptide fragments" are derived from about residues 61 to about 90 and from 61 to about 75 of the human alpha synuclein having a sequence selected from the group consisting of SEQ. ID. NO. 3 and SEQ. ID NO. 4. Support for this amendment may be found on page 5, lines 1-19. Entry of this amendment is therefore respectfully requested.

The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention has been reviewed. In view of the following comments applicants' attorney respectfully requests reconsideration of this rejection.

In claim 1 the claim has been clarified to more specifically claim the invention. Claim 1 has been amended to more clearly claim what applicants regard as their invention. The description of the longer enhancing peptide has been added to claim 1. The description of "peptide fragment" has also been incorporated from the specification to clarify the meaning of that term. Applicants' attorney respectfully submits that this amendment renders moot the rejection of claim 1-4.

The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the relevant art at the time the application was filed, that the inventors had possession of the claimed invention. In view of the following comments applicants' attorney respectfully requests reconsideration of this rejection.

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Applicants' attorney respectfully submit that The Examiner's *prima facie* case of unpatentability for lack of written description must be supported by specific findings and factual evidence that one skilled in the art would not consider the inventor to be in possession of the claimed invention. A general allegation that the claims are not described, or that the art is unpredictable, will not be sufficient to carry the burden of proof.

The PTO Written Description Guidelines lists some specific factors that are considered when evaluating evidence of possession and support for the claim scope. In general, any combination of these factors that identify and distinguish the claimed invention should be sufficient to demonstrate possession of the invention and satisfaction of the written description requirement.

Level of skill and knowledge in the art;

Disclosure of partial structure;

Disclosure of physical/chemical properties;

Functional characteristics/correlation between structure and function;

Method of making the claimed invention.

The present rejection of claims 1-4 for lacking an adequate written description does not discuss the relevant level of skill and knowledge in the art for biological inventions. The present rejection of claims 1-4 for lacking an adequate written description does not discuss whether a partial structure of is provided for the "peptide fragments". The present rejection of claims 1-4 for lacking an adequate written description does not discuss the relevant functional characteristics/correlation between the fragments and their functions. Applicants' attorney respectfully submits that a *prima facie* case of unpatentability for lack of written description must be supported by specific findings and factual evidence that one skilled in the art would not consider the inventor to be in possession of the claimed invention. A general allegation that the claims are not described, or that the art is unpredictable, will not be sufficient to carry the burden of proof. Applicants' attorney respectfully submits that a *prima facie* case of unpatentability for lack of written description has not been established with regards to claims 1-4.

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With regards to claims 1-4, applicants' attorney respectfully submits that an adequate written description has been provided. The peptide from which the peptide fragment are to be derived is described on page 5, lines 14-19. It is well within the skill of one of ordinary skill in the art to make fragments of the peptides provided on page 5, lines 14-19. Additionally, the function of the peptides is described in the specification to enhance the aggregation of alpha synuclein. SEQ ID. NO. 4 would also appear to be an example of one such "peptide fragment" derived from SEQ. ID. NO. 3. Applicants' attorney respectfully submits that it would be well within the skill of one of skill in the art to screen fragments from these peptides (SEQ. ID. NO. 3 and SEQ.ID. NO. 4) for the desired activity using the aggregation test described in Example 3. Consequently, applicants' attorney respectfully submits that there is adequate written description to demonstrate to one of ordinary skill in the art that the applicants had possession of the invention. Accordingly, applicants' attorney respectfully submit that even if the Examiner were able to present a *prima facie* rejection of claims 1-4, that this rejection would be in error for the reasons stated above.

The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Biere et al. (US 6,184,351) in view of Murray et al. and Levine has been reviewed, however, applicants' attorney respectfully requests reconsideration and withdrawal of this rejection.

The invention as currently claimed utilizes an enhancing peptide to expedite the rate at which assays related to alpha synuclein aggregation can be performed. In Figures 1 and 2 of the present invention the aggregation of alpha synuclein could be followed quite quickly over a much shorter time course than the prior art methods of assaying alpha synuclein aggregation or disaggregation. This improved time course is believed to be due to the addition of an enhancing peptide.

Claim 1 as amended now indicates that an enhancing peptide has been added to the synuclein solution. Page 5 of the specification discusses the effect of *separately* providing synthetic peptides or peptides fragments of 61-90 and 61-75 of alpha synuclein to enhance the aggregation of alpha synuclein solution. As is apparent from the specification and Figures using peptides with at least the 61-75 amino acid residues of alpha synuclein up to peptides with the

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length of 61-90 amino acids residues of alpha synuclein significantly improves the aggregation rate of alpha synuclein. See page 5 of the specification and Figures 1 and 2. Applicants attorney respectfully submits that in view of the amendments to claim 1 that it can no longer be argued that human recombinant NACP/I-synuclein composition taught by Biere et al. reads on claims 1-4 as was argued in the office action of July 25, 2006.

Biere et al. in Figures 3, 6 and 7 follows alpha synuclein aggregation for hundreds of hours or days. In column 6, line 60 through column 7, line 5, Biere et al. discusses the long period of time involved in the aggregation of alpha synuclein. Similarly, Murray et al. had to continuously agitate at 37 C for 2 days to induce fibrilization to perform the assay described by Murray. Neither document discloses adding enhancing peptides to the solution. Accordingly, applicants' attorney respectfully submits that neither Biere et al. nor Murray et al. suggest or disclose the applicants' invention as claimed. Although LeVine does add that the aggregation of Thioflavine T can be measured at about 485 nm (specifically 482 nm); LeVine does not disclose separately adding enhancing peptides. Therefore, applicants' attorney respectfully that the addition of the enhancing peptide to the assay as described in claim 1 is patentable over the Biere et al., Murray et al. and LeVine.

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Applicants respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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